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EXAMINER

LEAVITT, MARIA GOMEZ

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1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/839,536	Applicant(s) APT ET AL.	
	Examiner MARIA LEAVITT	Art Unit 1633	

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 April 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 31 July 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07-31-01;05-29-02;05-21-08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This is the First Office Action on the Merits of the application filed 23 April 2001, which claims benefit of the US provisional application 60/198,74 filed 21 April 2000.

Claims 1-22, as originally filed, are pending. Applicants' election of Group I, drawn to drawn to an algal cell comprising a chimeric DNA encoding a transport protein, i.e., claims 1-10, in Applicants' response filed on 04-11-2008 is acknowledged. Claims 11-22 are withdrawn from consideration as being directed to non-elected inventions pursuant to 37 CFR 1.14(b), there being no allowable generic or linking claim. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

The requirement is still deemed proper and made final.

Therefore, claims 1-10 are currently under examination to which the following grounds of rejection are applicable.

Statutory Double Patenting — 35 U.S.C. 101

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 1-22 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-22 of copending U.S. Patent Application No. 11,842,887, claims 1-22 of copending U.S. Patent Application No. 11,842,888 and claims 1-22 of copending U.S. Patent Application No. 11,842,898. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-22 of U.S. Application No. '887, U.S. Application No. '888 and U.S. Patent Application No.'898 are identical to the respective claims of the instant application because their claims are all drawn to an algal cell comprising a chimeric DNA encoding a transport protein, namely claims 1-10, a method of producing an algal biomass, namely claims 11-17 and a method for the heterotrophic conversion of cells and for selecting transformed cells from a population, namely claims 18-22.

Claim Objection

Claims 1 and 6 are objected to because of the following informalities: The word "algal" should be preceded by the indefinite article "an" and not "a". Appropriate correction is required.

Additionally, claim 1 is objected to because of the phrase "the substantial absence of light" which is grammatically incorrect as there is not a proper antecedent base for the definite article "the" within the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 102(b)

The phrase "substantial absence of light" is defined in the specification as filed, at page 14, lines 25-29 as the growing or culturing "under light conditions under which phototrophic cells would be unable to grow **or would grow very poorly**" and at page 15, lines 4-5, the phrase

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“substantial absence of light” is defined as “level of illumination which would **be growth limiting**”. The instant claims do not place a closed limitation in reference to what extent the algal cell grows in the absence of light. Therefore, an algal cell growing for 8-hr in the dark reads on the instant invention. To the extent that the claimed invention embraces an algal cell which grows in the “substantial absence of light”, the following rejection applies.

The following is a quotation of the appropriated paragraphs of 35 U.S.C. 102 that forms the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 8, and 10 are rejected under 435 U.S.C. 102(b) as being anticipated by Hallmann et al., (1996, *Proc. Natl. Acad. Sci*, pp. 669-673, of record).

Hallmann et al. teaches transgenic *Volvox* algae able to synthesize a functional hexose/H⁺ symporter (HUP1) from *Chlorella* under the control of the constitutive *Volvox* beta-tubulin promoter. Transformants *Volvox* algae were grown in an 8-h dark/ 16-h light cycle, (p. 669, col. 2, paragraph 4; p. 623, col. 2; p. 671, col. 1, last paragraph). Note that 8h dark is substantially dark since the instant claims do not place any limitation in reference to any dark/light cycle. Additionally, Hallmann et al. discloses that *Volvox* algae exhibited survival after prolonged incubation in the dark in a glucose –containing medium in the absence of light in contrast to the corresponding wild type *Volvox* algae (col. 1, last paragraph), reading on growth sustained for longer periods in the dark because of the presence of the hexose transporter in the transformant algae in relation to absence of the same chimeric DNA. **Current claims 1, 3, 5, 8 and 10.** Note that transformants *Volvox* algae exhibited survival after prolonged incubation in the

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dark in a glucose –containing medium because of the import of glucose as the source of carbon and energy in the absence of light in contrast to their wild type *Volvox* algae, said property reading also on a transformed algae able to grow heterotrophically e.g., an external source of organic compounds is used in the absence of light. **Current claim 6.** Also note that as the Hallmann et al. publication teaches *Volvox* algae expressing the an heterologous HUP1 transporter, then any activity activity resulting from the expression of the HUP1 protein such as supporting heterotrophic growth of the cell is is inherently anticipated because the structure of the algal cell is the same.

Thus, absent evidence to the contrary, the algal cell of Hallmann anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallmann et al., (1996, *Proc. Natl. Acad. Sci*, pp. 669-673, of record) in view of Dunahay et al., (*J. Phycol.* pp. 1004-1012, of record) and further in view of Fisher et al., (1999, *J. Phycol.* pp. 113-120, of record).

Hallmann et al. teaches transgenic *Volvox* algae able to synthesize a functional hexose/H⁺ symporter (HUP1) from the unicellular alga *Chlorella* under the control of the constitutive *Volvox* beta-tubulin promoter. Transformants *Volvox* algae were grown in an 8-h dark/ 16-h light cycle, (p. 669, col. 2, paragraph 4; p. 623, col. 2; p. 671, col. 1, last paragraph). Note that 8h dark is substantially dark since the claims do not place any limitation in reference to a dark/light cycle. Additionally, Hallmann et al. discloses that *Volvox* algae exhibited survival after prolonged incubation in the dark in a glucose –containing medium in the absence of light in contrast to the corresponding wild type *Volvox* algae (col. 1, last paragraph), reading on growth sustained for longer periods in the dark because of the presence of the hexose transporter in the transformant algae in relation to absence of the same chimeric DNA. (**Current claims 1**). Also

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note that transformants *Volvox* algae exhibited survival after prolonged incubation in the dark in a glucose –containing medium because of the import of glucose as the source of carbon and energy in the absence of light in contrast to their wild type *Volvox* algae, reading also on a transformed algae able to grow heterotrophically e.g., an external source of organic compounds is used in the absence of light. **(Current claim 6).**

Hallmann et al. does not specifically teach transforming a microalgal cell.

However, at the time the invention was made, Dunahay discloses two species of diatoms, (e.g., microalgal cells), e.g., *C. cryptica* and *Navicula saprophila* NAVIC1 Lange-Bertalot and Bonik (*N. saprophila*), that were genetically transformed by introducing plasmid vectors containing the heterologous *Escherichia coli* neomycin phosphotransferase II (*nptII*) gene (abstract; p. 1005, col. 1, paragraph 2). Likewise, Fisher et al., teaches transformation of diatom *Cylindrotheca fusiformis* (*C. fusiformis*) with hexose/H⁺ symporter (HUP1) from *Chlorella*. Furthermore, Fisher et al, discloses that the transporter was functionally incorporated into the membrane allowing *C. fusiformis* to take up labeled glucose and glucosamine (p. 114, col. 1 paragraph 2) **(Current claims 2 and 7).**

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made, to transfer the hexose/H⁺ symporter (HUP1) from *Chlorella* used to transform *Volvox* algae as taught by Hallmann et al. into any other microalgal cell which grows in the substantial absence of light, particularly because Hallmann discloses survival of transgenic *Volvox* algae after prolonged incubation in the dark in a glucose –containing medium, Dunahay exemplifies transformation of two diatom species with heterologous genes and, furthermore, Fisher et al., successfully exemplifies transformation of a third diatom species with

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the functional hexose/H⁺ symporter (HUP1) from *Chlorella*. The manipulation of previously identified DNA fragments and cell transformation systems of green algae, diatoms and red algae is within the ordinary level of skill in the art of molecular biology. Thus it would have been obvious to a person of ordinary skill in the art to transfer the functional hexose/H⁺ symporter (HUP1) from *Chlorella* into any other microalgal cell in an attempt to improve the uptake of glucose and increased survival after prolonged incubation in the dark in a glucose –containing medium, as a person with ordinary skill has good reason to pursue the known options within his grasp. One of ordinary skill in the art would have had a reasonable expectation of success in generating an algal cell which grows in the substantial absence of light, said cell comprising chimeric DNA encoding a protein which will transport a catabolizable carbon source into the algal cell by combining the detailed teachings of Hallmann, Dunahay and Fisher.

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallmann et al., (1996, *Proc. Natl. Acad. Sci*, pp. 669-673, of record) in view of Dunahay et al., (*J. Phycol.* pp. 1004-1012, of record) and further in view of Fisher et al., (1999, *J. Phycol.* pp. 113-120, of record) as applied to claims **1, 2, 6 and 7 above** and further in view of Lemoine et al., (1999, *FEBS Letters* pp. 325-330),

The teachings of Hallmann, Dunahay and Fisher are outlined in the paragraphs above. The combined disclosure fails to teach chimeric DNA encoding a disaccharide transporter.

However, at the time the invention was made, Lemoine et al., discloses that heterotrophic (or sink) organs in plants rely on the supply of photosynthates, mainly sucrose (e.g., disaccharide made of made from glucose and fructose), that enter the plant through specific carriers.

Moreover, Lemoine et al., discloses that the cloning of the SUT1 gene encoding sucrose carrier

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by yeast complementation was the basis for identifying sucrose carriers in other yeast species. Furthermore, Lemoine et al., discloses a cDNA encoding a sucrose transporter-like protein, specifically expressed in the pollen of tobacco plants.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made, to transfer the functional hexose/H⁺ symporter (HUP1) from *Chlorella* used to transform *Volvox* algae as taught by Hallmann et al. into any other microalgal cell which grows in the substantial absence of light, particularly because Hallmann discloses survival of transgenic *Volvox* algae after prolonged incubation in the dark in a glucose – containing medium, Dunahay exemplifies transformation of two diatom species with heterologous genes and, furthermore, Fisher et al., successfully exemplifies transformation of a third diatom species with the functional hexose/H⁺ symporter (HUP1) from *Chlorella*. Moreover, it would have been *prima facie* obvious for one of ordinary skill in the art to determine whether both monosaccharide and disaccharide transporters are present in an algal cell to transport a catabolizable carbon source, e.g., hexose or sucrose and to study what type of transporter contributes to the algae growth in the substantial absence of light, particularly because some algae are heterotrophs and Lemoine et al., discloses that heterotrophic (or sink) organs in plants rely on the supply of sucrose. The manipulation of previously identified DNA fragments and cell transformation systems of green algae, diatoms and red algae is within the ordinary level of skill in the art of molecular biology. Thus it would have been obvious to a person of ordinary skill in the art to transfer the functional hexose/H⁺ symporter (HUP1) from *Chlorella* into any other microalgal cell in an attempt to improve the uptake of glucose and increased survival after prolonged incubation in the dark in a glucose –containing medium, as a

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person with ordinary skill has good reason to pursue the known options within his grasp. One of ordinary skill in the art would have had a reasonable expectation of success in generating an algal cell which grows in the substantial absence of light, said cell comprising chimeric DNA encoding a protein which will transport a catabolizable carbon source into the algal cell by combining the detailed teachings of Hallmann, Dunahay, Fisher and Lemoine.

Conclusion

Claims 1-10 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633